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| EXAMINER | |
|---|---|
| CHIN, BRAD Y | |
| **ART UNIT** | **PAPER NUMBER** |
| 1744 | |

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/687,847 | TREIMAN, MICHAEL T. | |
| | Examiner | Art Unit | |
| | Brad Y. Chin | 1744 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☒ Claim(s) *36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/14/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

***Specification***

The disclosure is objected to because of the following informalities: On page 8 of the specification in paragraph [0028], Applicant designates the valve of eductor 20 with duplicate reference number, "20". On page 8 of the specification in paragraph [0029], Applicant designates the male end of the metering tip with reference number, "83". It is believed Applicant meant to use reference number, "86". Appropriate correction is required.

***Claim Objections***

Claim 36 is objected to because of the following informalities: Applicant improperly uses the word, "apparatus" in describing claim 1, where Applicant should have used the word, "method" in describing claim 1. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 7-8, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Sand et. al. [U.S. Patent No. 6,655,401].

Regarding claim 1, Sand teaches a method for diluting a concentrated solution of sterilant for sterilizing instruments or equipment comprising the steps of:

providing an eductor (single device 32 for selectively educting one or more chemical fluids for mixing with a motive fluid or eductor 92), the eductor comprising a

metering tip (See Specification, col. 5, lines 1-7 – metering tip (not shown) for controlling the dilution ratio of the chemical fluid) having a first orifice size (See Specification, col. 5, lines 1-7 – metering tip comprises an orifice allowing the chemical fluid to flow from the chemical fluid reservoir to the chemical inlet port), a chemical inlet port (chemical port 94), and a water inlet port (See Fig. 2 – water inlet port on the top of single device 32 at end of motive fluid conduit 36);

hooking a container containing concentrated sterilant to the chemical inlet port of the eductor (See Specification, col. 5, lines 4-7 – reservoir containing the chemical fluid (not shown) connected to the chemical inlet port of the eductor by use of a chemical fluid conduit);

hooking a water supply source to the water inlet port of the eductor (See Specification, col. 2, line 6 – pressurized water supply at water inlet 16), the water supply source comprising a regulating valve for regulating a working pressure of the water supply (See Specification, col. 4, line 23 – inlet valve 34 regulating the working pressure of the water supply);

activating the eductor to mix water and concentrated sterilant to a desired admixture containing a volume of sterilant to a volume of water (single selection control 52 for selecting [activating] the mixing and for simplifying use of the dispenser for the user)

adjusting the admixture by varying the volume of the sterilant to the volume of water by varying at least one of the metering tip to one having a second orifice size or the working pressure of the water supply to the eductor (See Specification, col. 5, lines 1-7 – typically a metering tip (not shown) is inserted into the chemical port 94 for controlling the dilution ratio of the chemical fluid in coordination with the dimensional

sizing of the eductor; See Specification, col. 4, line 23 – inlet valve 34 allows the user to regulate the working pressure of the motive fluid); and

using the admixture to sterilize an instrument for use in treating a subject (See Specification, col. 4, lines 15-22 – a suitable application for dispenser 30 includes dispensing chemical fluids such as a disinfectant, e.g. to sterilize an instrument for use in treating a subject).

Regarding claims 7, Sand teaches the method according to claim 1, further comprising the steps of providing a second eductor (second eductor 96) and hooking a container containing at least one of a disinfectant (See Specification, col. 4, line 15-22 – one suitable application identifies dispensing chemical fluids such as disinfectants), a sporicide, a biocide, a virucide, or a fungicide to a chemical inlet port (chemical port 98) of the second eductor (second eductor 96).

Regarding claim 8, Sand teaches the method according to claim 1, further comprising a barb assembly connected to the eductor's chemical inlet port and the metering tip is connected to the barb assembly (See Fig. 1 of prior art where metering tip is to be inserted, denoted by dotted lines, into the orifice in the barb assembly attached and projecting laterally from the side of eductors 18 and 20). It is also common knowledge to one of ordinary skill in the art to use metering tips in conjunction with barb assemblies, which are attached to the inlet ports of the eductors, to control the dilution ratio of the chemical fluid(s) entering the eductor.

Regarding claim 36, Sand teaches the method according to claim 1, wherein the concentrated sterilant is one of a concentrated disinfectant, a concentrated antiseptic, a

concentrated sporicide, a concentrated biocide, a concentrated virucide, or a concentrated fungicide (See Specification, col. 4, line 15-22 – one suitable application identifies dispensing chemical fluids such as disinfectants. The disinfectant could be characterized as concentrated because it is being diluted with water and potentially another chemical fluid, e.g. a pH adjusting agent).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 26 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sand et. al. [U.S. Patent No. 6,655,401].

Regarding claim 26, Sand teaches a method for dispensing an admixture of fluid and water in a proportioning and dispensing unit comprising the steps:

(a) selecting a first metering tip comprising a first orifice size and coupling the metering tip to a chemical inlet port of an eductor (See Specification, col. 5, lines 1-4),

said eductor further comprising a water inlet port and an outlet port (See Fig. 2 inlet near inlet valve 34 and outlet 48, respectively);

(b) connecting the water inlet port to a water supply source (motive fluid received at inlet valve 34), said water supply source comprising a pressure regulator having a first water pressure set point (inlet valve 34);

(c) selecting a first hose comprising a hose length (chemical fluid conduit with a length having a first and second end, where the first end is connected to the metering tip – See Specification, col. 5, lines 1-7);

(d) activating the eductor to produce the admixture of fluid and water at the outlet port (single selection control 52 for selecting the mixing, i.e. activating and de-activating the mixing controls of the eductor – See Specification, col. 4, lines 38-45); and

(e) de-activating the eductor to stop producing the admixture at the outlet port (single selection control 52 for selecting the mixing, i.e. activating and de-activating the mixing controls of the eductor – See Specification, col. 4, lines 38-45).

Sand fails to teach the method comprising the steps of (1) placing a holding container at the outlet port of the eductor for receiving an output stream from the eductor; (2) selecting the first hose comprising unit gradations along at least a portion of the hose length; (3) filing the hose length with a quantity of fluid to a starting fluid level; (4) determining an amount of fluid dispensed from the eductor; (5) determining the percent ratio of fluid dispensed; and (6) adjusting the dilution ratio by changing the metering tip position or water pressure set point if the percent ratio of chemical fluid to water is not as desired.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for a holding container to be placed at the outlet port of the eductor for receiving the output stream of the admixture because Sand teaches that the mixed

fluids, e.g. the admixture, are emitted from the device through the outlet and hose connected to the outlet and it would have been obvious that the user would desire to provide a holding container for storing and/or transporting the resulting diluted admixture.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to mark the chemical fluid conduct with unit gradations along at least a portion of the hose length, filing the hose length with a quantity of chemical fluid to a starting fluid level, and determining an amount of fluid dispensed from the eductor by determining the beginning and ending liquid level differential from the unit gradations because the aforementioned procedures are commonly used in scientific procedures involving pipeting volumes of liquid or measuring volume differentials on graduated cylinders or conduits. It would have been obvious to fill a marked chemical fluid conduit with the concentrated chemical fluid to a beginning level characterized by a first unit gradation on the hose length and then upon dispensing an amount of chemical fluid into the eductor, the user could identify the amount of chemical fluid dispensed by identifying the liquid level differential from the unit gradations on the hose length.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to then determine the percent ratio of chemical fluid dispensed and accordingly adjust the dilution ratio by changing the metering tip position or water pressure set point, if the percent ratio of chemical fluid to water is not as desired, because it would have been an obvious calculation, performed in common scientific procedures, to calculate the percent ratio of chemical fluid to water mixed in the eductor, and then appropriately adjusting one of the two variables, e.g. the metering tip position or the water pressure set point, to recalibrate the mixing ratios of the chemical fluid and water in the eductor for the desired diluted sterilant concentration.

Regarding claims 31 and 32, Sand teaches the method for diluting a concentrated solution of sterilant for sterilizing instruments or equipment as identified in claim 1 above. Sand fails to specifically teach the method further comprises the step of adjusting the working pressure up or down while leaving the metering tip with the first orifice size alone to vary the admixture of sterilant and water. Conversely, Sand fails to specifically teach the method further comprises the step of adjusting the metering tip to one having a second orifice size while leaving the working pressure alone to vary the admixture of sterilant and water.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to control the dilution ratio of the admixture by either (1) adjusting the working pressure of the water supply up or down while leaving the metering tip with the first orifice size alone or (2) adjusting the metering tip to one having a second orifice size, e.g. the orifice as part of the eductor, while leaving the working pressure alone because the eductor provides the user with the ability to control the amount of motive fluid and/or chemical fluid that enters the eductor for mixing. Sand teaches that in some applications, the selection control includes a position where no mixed fluids are emitted from the outlet and thus the inlet valve may be omitted or not routinely used (See Specification, col. 4, lines 42-44). Sand provides the motivation or teaching that the functionality of the eductor provides the user with the ability to control whether the metering tip is used for controlling the amount of chemical fluid received by the eductor or control whether the inlet valve is activated for controlling the amount of working pressure of motive fluid received by the eductor. Accordingly, it would have been obvious to one of ordinary skill with knowledge of eductor controls to adjust the working pressure of the water supply while leaving the metering tip alone to control the mixing of

the admixture for an appropriate desired concentration or to adjust the metering tip to one having a second orifice size while leaving the working pressure alone.

3. Claims 2-3, 5-6, 9-13, 15-19, 21-25, and 27-30, and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sand in view of Wachman et. al. [U.S. Patent No. 5,242,323].

Regarding claim 10, Sand teaches a method for diluting a concentrated chemical solution with water for use in a health care facility comprising the steps of:

providing an eductor housed in a housing (single device [eductor] 32 or eductor 92 in dispenser 30);

adjusting the eductor's output by adjusting a regulated valve to adjust a water supply pressure to a first pressure (adjusting inlet valve 34 to regulate the working pressure of the water supply) and adjusting a chemical inlet back pressure by selecting a metering tip having a first orifice size (See Specification, col. 5, lines 1-7 – metering tip (not shown) with an orifice inserted into the chemical port 94 for controlling the dilution ratio of the chemical fluid);

hooking an inlet connected to a container containing the concentrated chemical solution to the eductor's chemical inlet port (See Specification, col. 5, lines 4-7 – reservoir containing the chemical fluid (not shown) connected to the chemical inlet port of the eductor by use of a chemical fluid conduit);

hooking an inlet line from a water supply source downstream of the regulating valve to the eductor's water inlet port (See Fig. 2 – motive fluid conduit 36 from a pressurized water supply connected to eductor's water inlet port); and

activating the eductor so that water flows through the water inlet port and concentrated chemical solution flows through the chemical inlet port (single selection control 52 for activating the mixing and for simplifying use of the dispenser).

Sand fails to teach the method further comprising outputting the admixture into a holding container and applying the admixture to a surface inside a health care facility.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a holding container for the outputting admixture. A holding container provides the user with the ability to store and transport the diluted solution of sterilant.

Wachman et. al. [U.S. Patent No. 5,242,323]

In the specification on page 10, Applicant identifies the sterilant composition described in Wachman. Wachman teaches that the sterilant composition can be used on "hard" or "environmental" surfaces (non-absorbing) such as medical or dental equipment for which previously steam sterilization or treatment with ethylene oxide were employed (See Specification, col. 4, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wachman with Sand because Sand teaches the use of a dispenser, comprising multiple eductors, to dilute a concentrated sterilant solution for disinfecting applications. Disinfectants, such as those identified in Wachman, are commonly used to sterilize surfaces, instruments, and various other contaminated areas, such as areas inside a health care facility. Accordingly, Sand provides the motivation for application of the dispenser to dispense an admixture of diluted sterilant, such as Wachman's, to a surface inside a health care facility.

Regarding claim 19, Sand teaches an apparatus for diluting a concentrate comprising:

a proportioning and dispensing unit comprising at least two eductors (dispenser 30 with first eductor 92 and second eductor 96), wherein a first eductor comprises a first chemical inlet port ([first] chemical inlet port 94), a second chemical inlet port ([second] chemical inlet port 98), a motive source inlet port (See Fig. 2 – motive fluid conduit 36 from a pressurized water supply connected to eductor's water inlet port), and an outlet port (outlet 48);

a first container containing a concentrate having a container outlet port and a first hose connecting the container outlet port to the first chemical inlet port (See Specification, col. 5, lines 1-7 – reservoir containing the chemical fluid (not shown) connected to the chemical inlet port of the eductor by use of a chemical fluid conduit);

a line connecting a motive source to the motive source inlet port (motive fluid conduit 36), the line comprising a regulating valve for regulating pressure supplied by the motive source (inlet valve 34);

a third hose (hose 50) for connecting to the outlet port (outlet 48) of the eductor (device 32); and

wherein a fist metering tip is removably received in the first chemical inlet port and a second metering tip is removably received in the second chemical inlet port (See Specification, col. 5, lines 1-13 – metering tips (not shown) inserted [removably received] into the [first] chemical port 94 of first eductor 92 and the [second] chemical port 98 of second eductor 96, respectively).

Sand fails to teach a method further comprising a push button for opening a valve on the first eductor so as to permit motive source to flow through the first eductor.

Rather, Sand teaches that the device 32 includes a single selection control, depicted as lever 52, for selecting the mixing.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to substitute a push button for opening a valve on the first eductor permitting a motive source to flow through the first eductor because Sand provides the motivation for a single selection control to provide the user with a simplified control means, reducing the likelihood of control or mixing error (See Specification, col. 4, lines 39-45). Accordingly, it would have been obvious to substitute a push button in the place of lever 52 to control the dispenser.

Sand further fails to teach a method further comprising a second container containing a pH adjusting agent having a container outlet port and a second hose connecting the container outlet port to the second chemical inlet port.

Sand identifies the use of a second container comprising an outlet port and a second chemical fluid conduit connecting the container to the second chemical inlet port 98 (See Specification, col. 5, lines 8-13); however, Sand does not specifically identify that the second chemical element is a pH adjusting agent.

Wachman teaches a sterilant composition that includes a concentrated sterilant, water, and a pH adjusting agent (See Specification, col. 4, lines 23-33 – "typical embodiment of the present invention comprises: alkylbenzyldimethylammonium chloride, cetyldimethylethylammonium bromide, glutaraldehyde, Isopropyl alcohol, propylene glycol, sodium nitrite, tetrasodium ethylenediamine tetraacetate, and water).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the sterilant composition of Wachman into the apparatus of Sand because Sand provides the motivation for an apparatus which functions to dilute a concentrated sterilant composition. Sand provides a motive fluid

and two eductors, one for the concentrated sterilant composition and one for a second chemical fluid, e.g. in this case, the pH adjusting agent identified in Wachman.

Regarding claim 27, Sand teaches a method for dispensing an admixture of concentrated chemical solution and water in a proportioning and dispensing unit comprising:

mounting two eductors to a housing and mounting (first eductor 92 and second eductor 96 mounted in dispenser 30), the two eductors having a common water inlet header (motive fluid passage 120);

connecting a first chemical to a chemical inlet port of the first eductor (See Specification, col. 5, lines 1-7);

connecting a second chemical to a chemical inlet port of the second eductor (See Specification, col. 5, lines 8-14);

connecting a water supply line to the common water inlet header (See Specification, col. 4, line 23); the water supply line comprising a regulating valve (inlet valve 34);

activating at least one of the first eductor or the second eductor to produce an admixture of at least one of the first chemical and water or the second chemical and water (single selection control 52 – See Specification, col. 4, lines 38-45); and

wherein the chemical inlets of the first and second eductors each comprises a metering tip having an orifice (metering tips (not shown) – See Specification, col. 4, lines 1-14).

Sands fails to teach that the housing is mounted in a health care facility.

In the specification on page 10, Applicant identifies the sterilant composition described in Wachman. Wachman teaches that the sterilant composition can be used

on "hard" or "environmental" surfaces (non-absorbing) such as medical or dental equipment for which previously steam sterilization or treatment with ethylene oxide were employed (See Specification, col. 4, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wachman with Sand because Sand teaches the use of a dispenser, comprising multiple eductors, to dilute a concentrated sterilant solution for disinfecting applications. Disinfectants, such as those identified in Wachman, are commonly used to sterilize surfaces, instruments, and various other contaminated areas, such as areas inside a health care facility. Accordingly, Sand provides the motivation for application of the dispenser to dispense an admixture of diluted sterilant, such as Wachman's, to a surface inside a health care facility.

Regarding claim 5, Sand teaches a method for diluting a concentrated solution of sterilant for sterilizing instruments or equipment as identified in claim 1 above.

As identified in the explanation for claim 10 above, in view of Wachman and Sand, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further teach the method comprising the step of mounting the eductor in a health care facility.

Regarding claims 2, 11, 21, and 28 Sand and Wachman teach the methods and apparatus as identified in claims 1, 10, 19, and 27 above, respectively. Wachman further teaches the sterilant composition wherein the concentrated sterilant is a 50% or less by weight solution of glutaraldehyde to water (See Specification, col. 10, lines 51-57 – Example A).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the sterilant composition of Wachman as identified in Example A because such a diluted sterilant composition, mixed by the methods and apparatus of claims 1, 10, 19, and 27, respectively, would allow the user to produce a sterilant concentration appropriate for specific sterilizing applications.

Regarding claims 3, 13, 29, and 30 Sand and Wachman teach the methods as identified in claims 1, 10, and 27 above, respectively. Sand teaches a second eductor 96 comprising a second chemical inlet [port] 98 and wherein a container containing a second chemical fluid is connected to the second chemical inlet port (See Specification, col. 5, lines 8-14). Wachman teaches a sterilant composition that includes a concentrated sterilant, water, and a diluent, such as a pH adjusting agent (See Specification, col. 4, lines 23-33 – "typical embodiment of the present invention comprises: alkylbenzyldimethylammonium chloride, cetyldimethylethylammonium bromide, glutaraldehyde, Isopropyl alcohol, propylene glycol, sodium nitrite, tetrasodium ethylenediamine tetraacetate, and water).

As explained for claim 19 above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the sterilant composition of Wachman into the apparatus of Sand because Sand provides the motivation for an apparatus which functions to dilute a concentrated sterilant composition. Sand provides a motive fluid and two eductors, one for the concentrated sterilant composition and one for a second chemical fluid, e.g. in this case, a diluent, such as the pH adjusting agent identified in Wachman.

Regarding claim 30, it additionally would have been obvious to provide for the method of claim 27, wherein the first chemical is a 50% by weight of glutaraldehyde to water and the second chemical is a diluent (See rationale for claim 28 above).

Regarding claims 6 and 15, Sand and Wachman teach the method and apparatus as identified in claims 1 and 10 above, respectively. Sand and Wachman fail to teach the method further comprising the step of providing a pressure gauge downstream of the regulating valve.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a pressure gauge downstream of the regulating valve into Sand and Wachman because it is well known that pressure gauges provide the user with the ability to monitor the amount of pressure at a certain point, e.g. the point at which the pressure gauge is located. Because regulation of the motive fluid pressure is important in properly diluting the concentrated sterilant composition, the use of a pressure gauge downstream of the regulating valve (inlet valve 34 in Sand) at the point where the motive fluid enters the eductor would be an obvious addition to the methods of Sand and Wachman in properly mixing and diluting the concentrated sterilant composition.

Regarding claims 9 and 18, Sand and Wachman teach the methods as identified in claims 1, 3, 10, and 13 above, respectively. Wachman further teaches in Example 5 in the Specification, col. 5, the method wherein the admixture produced comprises about a 3.2% by weight of glutaraldehyde, about a 0.925% by weight of the pH adjusting agent, and a balance by weight of water.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the admixture sterilant composition of Wachman into the method of Sand because such an admixture would produce a sterilant concentration appropriate for specific sterilizing applications.

Regarding claims 12 and 22, Sand and Wachman teach the method and apparatus for diluting a concentrated chemical solution as identified in claims 10 and 19 above. Sand further teaches the method and apparatus wherein the eductor is equipped with a second metering tip comprising a second orifice size (See specification, col. 5, lines 1-14). Accordingly, both the first metering tip and the second metering tip of claim 19 each comprise an orifice.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate two metering tips for corresponding eductors because this would allow the user to control the mixing of two chemical fluid feeds into the eductor.

Regarding claims 16 and 25, Sand and Wachman teach the method and apparatus as identified in claims 10 and 19 above, respectively. Sand teaches a second eductor 96 with a second chemical reservoir containing a chemical fluid containing at least one of a disinfectant (See Specification, col. 4, line 15-22 – one suitable application identifies dispensing chemical fluids such as disinfectants), a sporicide, a biocide, a virucide, or a fungicide connected to a chemical inlet port 98 of the second eductor 96.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the concentrated sterilant composition to be a disinfectant, as identified with the constituents in Wachman, which are diluted through the method and

apparatus of Sand in producing a diluted sterilant composition suitable for specific disinfecting applications.

Regarding claims 17 and 23, Sand and Wachman teach the method and apparatus as identified in claims 10 and 19 above, respectively. Sand further teaches the method further comprising a barb assembly further connected to the eductor's chemical inlet port and the metering tip is connected to the barb assembly. Sand also teaches the apparatus wherein the first metering tip and the second metering tip each connects to a barb assembly. (See Fig. 1 of prior art where metering tip is to be inserted, denoted by dotted lines, into the orifice in the barb assembly attached and projecting laterally from the side of eductors 18 and 20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Wachman into the method and apparatus of Sand because it is common knowledge to one of ordinary skill in the art to use metering tips in conjunction with barb assemblies, which are attached to the inlet ports of eductors, to control the dilution ratio of the chemical fluid(s) entering the eductor.

Regarding claim 24, Sand and Wachman teach the apparatus as identified in claim 19 above. Sand teaches a third hose (hose 50) for connecting to the outlet port (outlet 48) of the eductor (device 32). Sand and Wachman fail to teach that the third hose is directed to a holding container for outputting an admixture into the holding container.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the third hose would be directed to a holding container for outputting an admixture into the holding container because Sand teaches that the mixed

fluids, e.g. the admixture, are emitted from the device through the outlet and hose connected to the outlet and it would have been obvious that the user would desire to provide a holding container for the outputting admixture. A holding container provides the user with the ability to store and transport the diluted solution of sterilant.

Regarding claims 37-39, Sand and Wachman teach the methods and apparatus as identified in claim 10, 19, and 27 above, respectively. Sand and Wachman fail to specifically teach that the concentrated chemical solution is a concentrated photochemical.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a concentrated photochemical as the chemical fluid because Sand and Wachman teach the methods and apparatus that selectively mix one or more chemical fluids. Accordingly, it would have been obvious to use almost any type of concentrated chemical fluid in the methods and apparatus of Sand and Wachman, e.g. a concentrated photochemical for the photography industry.

4. Claims 4, 14, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sand et. al. in view of Wachman et. al. as applied to claims 1, 10, and 19 above, and further in view of Dalhart et. al. [U.S. Patent No. 6,619,318].

Sand and Wachman teach the methods and apparatus as identified in claims 1, 10, and 19 above, respectively. Sand and Wachman fail to teach the methods and apparatus identified above wherein the regulating valve regulates the water supply source to a water pressure of less than 50 psi.

Dalhart teaches that is well known in the prior art that gravity feed systems have a number of shortcomings; one of which is the dilution ratio is adversely affected by

water pressure. Dalhart continues to teach that the typical water pressure often varies from 20-80 psi, with low-pressure 20-30 psi common in certain countries or remote facilities. As the water pressure varies, the dilution ration varies, since the amount of concentrated solution that is mixed is based on gravity and the size of the orifice.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Dalhart with that of Sand and Wachman for regulating the water supply source to a water pressure less than 50 psi because this motive fluid pressure would provide the proper mixing of sterilant, diluent, and water, creating a sterilant composition appropriate for specific sterilization applications.

5. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sand et. al. in view of Wachman et. al. as applied to claims 1, 10, and 19 above, and further in view of Stanley [U.S. Patent Publication No. 2004/0156744].

Regarding claims 33-35, Sand and Wachman teach the methods and apparatus as identified in claim 1, 10, and 19 above, respectively. Sand and Wachman fail to teach the methods and apparatus further comprising hooking the water supply source to an inlet of a booster pump and hooking a pump outlet to the water inlet port of the eductor.

Stanley teaches a cleaning and sterilizing device and method that utilizes a positive pressure pump to produce positive pressure flow, which provides a greater range of pressures. Stanley further teaches that positive pressure low provides both the pressure source and the fluid source at one location, simplifying connections and automation. Positive pressure is also safer because contaminants cannot be drawn into the device through leaks in the system (See Specification, p. 4, [0056]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Stanley into Sand and Wachman for providing a pump connected between the motive source and the regulating valve because as Stanley teaches the positive pressure flow would provide the user with a greater range of working pressures for the motive fluid. Sand provides the motivation for the control and regulation of the motive fluid pressure into the eductor, providing more control over the amount of motive fluid added in diluting the concentrated chemical fluid. It would have been an obvious modification to include the booster pump to create such a control means for regulating the pressure of the motive fluid into the eductor and allowing the user to control the dilution ratio of the diluted concentrated solution of sterilant.

***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Y. Chin whose telephone number is 571-272-2071. The examiner can normally be reached on Monday – Friday, 8:00 A.M. – 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden, can be reached at 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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byc
January 6, 2005

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